IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TENNESSEE
WESTERN DIVISION

CHERYL AUTIN, CAROL DIFFEE, and ABIGAIL GIVHAN, on behalf of themselves and others similarly situated,	)	
Plaintiffs,	)	
v.	)	**NO. 05-2213-M/An**
SOLVAY PHARMACEUTICALS, INC., and HAROLD H. SHELVIN, Ph.D,	)	
Defendants.	)	

ORDER DENYING PLAINTIFFS' MOTION FOR LEAVE TO AMEND COMPLAINT AND ORDER TO STRIKE

Before the Court is Plaintiffs' Notice of Filing of First Amended Federal Complaint and Alternative Motion for Leave filed on July 21, 2005. For the reasons set forth below, Plaintiff's Amended Complaint shall be stricken from the record and Plaintiffs' Alternative Motion for Leave shall be **DENIED**.

Background

In February of 2005, Plaintiffs commenced this action against Defendants in Tennessee State Court and filed an Amended Complaint on March 8, 2005. Thereafter, the Defendants removed this action to the United States District Court for the Western District of Tennessee based upon the Class Action Fairness Act and diversity jurisdiction and filed a Rule 12(b) Motion to Dismiss. In response, Plaintiffs filed a First Amended Federal Class Action Complaint and Request for Injunctive Relief on July 21, 2005. On that same day, Plaintiffs alternatively filed a Motion for Leave to Amend Complaint arguing that only a previous

amendment in federal court applies for the purposes of Federal Rule of Civil Procedure Rule 15(a), which allows a plaintiff to amend her pleadings once "as a matter of course" before the defendants serve a responsive pleading. Fed. R. Civ. P. 15(a). In the alternative, Plaintiffs argue that the liberal standards of Rule 15(a), under which leave to amend "should be freely granted," should apply and Plaintiffs should be allowed to amend their Complaint in the interest of justice. *Id.*

Analysis

Under Federal Rule of Civil Procedure 15(a), a plaintiff may amend his complaint once "as a matter of course" at any time before a defendant has served a responsive pleading. Any additional amendments, however, require leave of court. Fed. R. Civ. P. 15(a). "Following removal, federal courts recognize all prior pleadings, orders and other proceedings in the state court action and presume them valid." *Armstrong v. Unc-Lear Siegler, Inc.*, 1999 U.S. Dist. LEXIS 9821 2529, *8 (N.D.N.Y. March 1, 1999). In the instance case, Plaintiffs filed a First Amended Complaint on March 8, 2005, in state court and have thus already used their one amendment as a matter of course. If this Court were to allow Plaintiffs to amend their Complaint at this time without leave of court, it would deem Plaintiffs' prior amended complaint as invalid. This is something the Court is not willing to do and so Plaintiffs' First Amended Federal Complaint is ordered stricken from the record.

Plaintiffs also filed an Alternative Motion for Leave in order to amend their Complaint. A pleading may be amended "only by leave of court . . . and leave shall be freely given when justice so requires." Fed. R. Civ. P. 15(a). However, a "trial court may appropriately assess the legal sufficiency of a contemplated amendment in considering the propriety of granting leave to amend under Fed. R. Civ. P. 15(a) and deny the motion if amendment would be futile." *Kindle*

Building Co. v. Ford Motor Co., 17 F. Supp. 2d 701, 705 (N.D. Ohio 1997). When a Plaintiffs' claims are preempted by federal law, the motion to amend is futile and should be denied. *Adkins v. Unum Provident Corp.*, 191 F. Supp. 2d 956, 960 (M.D. Tenn. 2002); *Golden v. Kelsey-Hayes Co.*, 878 F. Supp. 1054, 1057 (E.D. Mich. 1995).

In the Amended Complaint, Plaintiffs advance two theories under which they believe they are entitled to relief. First, under their "Illegal Sales Theory," Plaintiffs claim that Defendants violated § 355 of the Food, Drug and Cosmetic Act ("FDCA") because Estratest is a new drug and had not received FDA approval. Second, Plaintiffs contend that Defendants represented that Estratest had been approved by the FDA when it had not been so approved and that this was a fraudulent and deceptive act. This theory is entitled the "Fraudulent Sales Theory."

The Illegal Sales Theory advanced by Plaintiffs is explicitly preempted by the FDCA. The FDCA provides various avenues for the marketing of drugs. GRASE drugs[1] and drugs made and manufactured in compliance with federal regulations prior to 1938 may be marketed without FDA approval but all other drugs are termed "new drugs" and must receive FDA approval. 21 U.S.C. §§ 321, 355. Plaintiffs claim is that Defendants violated the FDCA by marketing and distributing a drug that was neither a GRASE drug, nor manufactured prior to 1938, nor an FDA approved "new drug." Section 337(a) bars such private enforcement of the act and thus Plaintiffs may not bring a claim for violation of the FDCA on their own behalf. 21 U.S.C. 337(a) ("[A]ll such proceedings for the enforcement, or to restrain violatons, of [the FDCA] shall be by and in the name of the United States."); see also *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001) (Plaintiffs may not bring state law tort claims premised on violations of the FDCA.);

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[1]GRASE drugs are those that are "Generally Recognized as Safe and Effective" under 21 U.S.C. § 321(p)(2).

Cupek v. Medtronic, Inc., 405 F.3d 421 (6th Cir. 2005).

The Fraudulent Sales Theory is also preempted by the FDCA. "Preemption may be implied or inferred "where the scheme of federal regulation is sufficiently comprehensive to make reasonable the inference that Congress 'left no room' for supplementary state regulation," where the federal interest in regulating a certain area is dominant over any state interest or where enforcement of state laws would frustrate the federal regulatory objective. *Brown v. McNeil Laborotories, Inc.*, 1988 U.S. Dist. LEXIS 17441, *4 (W.D. Mich. 1988) (citing *Hillsborough County v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 713 (1985). Although Plaintiffs do not specifically cite to a particular provision of the FDCA that has been violated by the Defendants, a claim that the Defendants are deceptively marketing a drug as FDA approved when it is not so approved falls squarely within the purview of the FDA's enforcement power.

In § 355, the FDCA sets out the steps a drug manufacturer must follow before marketing a new drug. These steps are detailed and encompass information concerning the drug's components, its manufacturing, studies that have been conducted, and the proposed labeling of the drug. See 21 U.S.C. §355. Failure to comply with the FDCA's approval process while giving the general appearance of compliance through the drug's labeling or the books in which information concerning the drug is published appears to be a violation of § 355 and the FDCA and thus cannot form a cause of action for private individuals due to § 337(a) of the FDCA.

In addition to the preemption of the Fraudulent Sales Theory due to § 335 of the FDCA, § 331 prohibits a party from introducing or delivering into interstate commerce "any food, drug, device, or cosmetic that is adulterated or misbranded" or "misbranding" any drug in interstate

commerce.[2] 21 U.S.C. § 331. A misbranded drug is one whose label is "false or misleading in any particular." 21 U.S.C. § 352. Even if Plaintiff's Fraudulent Sales Theory was not preempted by § 355, it is preempted by § 331 because Plaintiffs claim that Defendants falsely represented that Estratest had been approved by the FDA by publishing information on Estratest without a proper disclaimer alerting the public that is was not FDA approved.

As such, because Plaintiff's two theories under which they seek relief are preempted by the Food, Drug and Cosmetic Act, their amendment is futile and thus their Motion for Leave to Amend is **DENIED**.

IT IS SO ORDERED.

S. Thomas Anderson

S. THOMAS ANDERSON

UNITED STATES MAGISTRATE JUDGE

Date: October 19, 2005

[2]Plaintiffs even assert in their amended Complaint, albeit not in the Fraudulent Sales Theory portion, that Defendants violated this section when they "delivered for introduction, and introduced into interstate commerce Estratest, which was a new drug for which no approval of new drug application was effective." Pl's First Amended Fed. Compl. at 8.

UNITED STATES DISTRICT COURT - WESTERN DISTRICT OF TENNESSEE

Notice of Distribution

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Honorable Samuel Mays
US DISTRICT COURT